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Applicants: Abraham J. Domb

Serial No.: 10/031,728  
35USC371 of PCT/IL00/00420

Art Unit: Not Yet Assigned

#6/I.D.S.

Filed: May 1, 2002

Examiner: Not Yet Assigned

For: *A BIODEGRADABLE POLYCATION COMPOSITION FOR DELIVERY OF AN ANIONIC MACROMOLECULE*

Assistant Commissioner for Patents  
Washington, D.C. 20231

**INFORMATION DISCLOSURE STATEMENT**

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicant submits an Information Disclosure Statement, including three (3) pages of Form PTO-1449 and copies of twenty-eight (28) documents cited therein, and a copy of the International Search Report mailed December 1, 2000 in PCT/IL00/00420, which corresponds to the above-identified application.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

**U.S. Patents**

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
3,225,012	12-21-1965	Black et al.	260-78
4,146,515	03-27-1979	Buikema et al.	260/9
5,312,967	05-17-1994	Kiely et al.	560/180

U.S.S.N.: 10/031,728  
 Filed: January 22, 2002  
 INFORMATION DISCLOSURE STATEMENT

5,329,044	07-12-1994	Kiely et al.	562/564
5,434,233	07-18-1995	Kiely et al.	527/310
5,473,035	12-05-1995	Kiely et al.	527/312
5,567,685	10-22-1996	Linden et al.	514/31
5,833,230	11-10-1998	Nakagawa et al.	271/121

#### Foreign Documents

<u>Number</u>	<u>Publication Date</u>	<u>Patentee</u>	<u>Country</u>
WO 93/25239	12-23-1993	Advanced Magnetics Inc.	PCT
WO 95/30020	11-09-1995	Immuno-Designed Molecules	PCT
WO 97/46223	12-11-1997	Genzyme Corp.	PCT
WO 98/01162 -	01-15-1998	Johns Hopkins Univ.	PCT
WO 98/27209	06-25-1998	Emory University	PCT
0 370 810	11-23-1989	Nippon Oil and Fats Co.	EP

#### Publications

AMSELEM, et al., "Lipospheres for Vaccine Delivery," in Microparticulate Systems for Drug Delivery (Berstein, et al., eds.), pp. 149-168, 1996.

BYK, et al., "Novel cationic lipids for gene delivery and gene therapy," *Exp. Opin. Ther. Patents* 8(9):1125-1141 (1998).

DOMB, et al., "Lipospheres for Controlled Delivery of Substances," in Nanosphere Delivery Systems (Benita, et al., eds.), pp. 377-410, 1996.

DOMB, et al., "Polymers in gene therapy," in Frontiers in Biological Polymer Applications (Ottenbrite, ed.) Technomic: Lancaster, Vol. 2, pp. 1-16 (1999).

KIELY, et al., "Hydroxylated nylons based on unprotected esterified D-glucaric acid by simple condensation reactions," *J. Am. Chem. Soc.* 116: 571-578 (1994).

LEDLEY, "Nonviral gene therapy: the promise of genes as pharmaceutical products," *Hum. Gene Ther.* 6(9): 1129-1144 (1995).

LIU, et al., "Sugar-containing polyamines prepared using galactose oxidase coupled with chemical reduction," *J. Am. Chem. Soc.* 121: 466-467 (1999).

MAO, et al., "DNA-chitosan nanospheres: derivitization and storage stability," *Proc. Intl. Symp. Control Rel. Bioact. Matter* 24: 671-672 (1997).

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PITHA, et al., "Detergents linked to polysaccharides: preparation and effects on membranes and cells," *Eur. J. Biochem.* 94(1): 11-18 (1979).

RICHARDSON, et al., "Evaluation of highly purified chitosan as a potential gene delivery vector," *Proceed Intl. Symp. Control Rel. Bioact. Matter* 24: 649-650 (1997).

TAKAKURA, et al., "Control of pharmaceutical properties of soybean tyrosine inhibitor by conjugation with dextran 1: synthesis and characterization," *J. Pharm. Sci.* 78(2): 117-121 (1999).

TRECO & SELDEN, "Non viral gene therapy," *Molec. Med. Today* 1(7): 299-348 (1995).

WALSH, et al., "Combination of drug and gene delivery by gelatin nanospheres for the treatment of cystic fibrosis," *Proc. Intl. Sym. Control. Rel. Bioact. Mater.* 24: 75-76 (1997).

YAMAOKA, et al., "Effect of cation content of polycation-type gene carriers on *in vitro* gene transfer," *Chemistry Letters*, 1171-1172 (1998).

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Filed: January 22, 2002  
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### Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicant invites the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicant is of the opinion that his claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Patrea L. Pabst  
Reg. No. 31,284

Dated: September 20, 2002

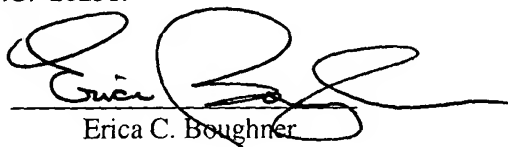
HOLLAND & KNIGHT LLP  
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**Certificate of Mailing under 37 C.F.R. § 1.8(a)**

I hereby certify that this Information Disclosure Statement, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Date: September 20, 2002



Erica C. Boughner

ATL1 #537484 v1

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				Application Number	10/031,728 35USC371 of PCT/IL00/00420
				Filing Date	May 1, 2002
				First Named Inventor	Abraham J. Domb
				Group Art Unit	
				Examiner Name	
Sheet	1	of	3	Attorney Docket Number	PG 101

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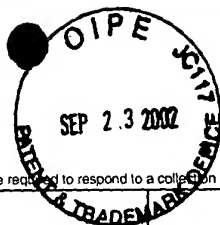
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>2</sup>
		Office. <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
		PCT	WO 93/25239	-	Advanced Magnetics Inc.	12-23-1993		
		PCT	WO 95/30020	-	Immuno-Designed Molecules	12-09-1995		
		PCT	WO 97/46223	*	Genzyme Corporation	12-11-1997		
		PCT	WO 98/01162	-	Johns Hopkins University	01-15-1998		
		PCT	WO 98/27209	-	Emory University	06-25-1998		
		EP	0 370 810	-	Nippon Oil and Fats Co.	11-23-1989		

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<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/031,728 35USC371 of PCT/IL00/00420
		Filing Date	May 1, 2002
		First Named Inventor	Abraham J. Domb
		Group Art Unit	
		Examiner Name	
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OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		AMSELEM, et al., "Lipospheres for Vaccine Delivery," in <u>Microparticulate Systems for Drug Delivery</u> (Berstein, et al., eds.), pp. 149-168, 1996.	
		BYK, et al., "Novel cationic lipids for gene delivery and gene therapy," <u>Exp. Opin. Ther. Patents</u> 8(9):1125-1141 (1998).	
		DOMB, et al., "Lipospheres for Controlled Delivery of Substances," in <u>Nanosphere Delivery Systems</u> (Benita, et al., eds.), pp. 377-410, 1996.	
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		LIU, et al., "Sugar-containing polyamines prepared using galactose oxidase coupled with chemical reduction," <u>J. Am. Chem. Soc.</u> 121: 466-467 (1999).	
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Application Number

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35USC371 of PCT/L00/00420

Filing Date

May 1, 2002

First Named Inventor

Abraham J. Domb

Group Art Unit

Examiner Name \_\_\_\_\_

Attorney Docket Number

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Sheet	3	of
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